DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3441. Misbranding of Benzedrine Sulfate tablets and Dexedrine Sulfate tablets. U. S. v. The Eckerd Drug & Notion Co., Edmond R. Anderson, Sr., and Charles F. Potts. Pleas of guilty. Fine of $100 against company suspended; fine of $100, plus costs, against each individual. (F. D. C. No. 30040. Sample Nos. 52070–K, 52098–K, 72183–K, 72220–K, 72415–K.)

INFORMATION FILED: March 5, 1951, Northern District of Ohio, against the Eckerd Drug & Notion Co., a corporation, Akron, Ohio, and against Edmond R. Anderson, Sr., secretary and general manager of the corporation, and Charles F. Potts, a pharmacist for the corporation.

INTERSTATE SHIPMENT: Fom the State of Pennsylvania into the State of Ohio, of quantities of *Benzedrine Sulfate tablets* and *Dexedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about October 28 and December 29, 1949, and January 13 and February 16 and 20, 1950, while the drugs were being held for sale at the Eckerd Drug & Notion Co., after shipment in interstate commerce, various quantities of the tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets being misbranded.

The Eckerd Drug & Notion Co. was charged with causing the acts of repacking and sale of the drugs involved in each of the five counts of the information; and, in addition, Edmond R. Anderson, Sr., in two of the counts, and Charles F. Potts, in one of the counts of the information, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use. Further misbranding, Sections 502 (b) (1) and (2), a portion of the repackaged *Benzedrine Sulfate tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and various portions of the repackaged *Benzedrine Sulfate tablets* and the *Dexedrine Sulfate tablets* failed to bear labels containing statements of the quantity of the contents.

DISPOSITION: March 30, 1951. Pleas of guilty having been entered, the court imposed a fine of $100 against the company, which fine was suspended by reason of insolvency. The court also imposed a fine of $100, plus costs, against each individual.

3442. Misbranding of thyroid tablets, Dexedrine Sulfate tablets, Benzedrine Sulfate tablets, phenobarbital tablets, and Amytal tablets. U. S. v. Arthur C. Moreland. Plea of nolo contendere. Imposition of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30024. Sample Nos. 61897–K, 61898–K, 77120–K, 77703–K, 77704–K, 77716–K.)

INFORMATION FILED: January 31, 1951, Western District of Arkansas, against Arthur C. Moreland, Ashdown, Ark.

INTERSTATE SHIPMENT: From the States of Missouri, Pennsylvania, and Indiana, into the State of Arkansas, of quantities of *thyroid tablets, Dexedrine Sulfate tablets, Benzedrine Sulfate tablets, phenobarbital tablets,* and *Amytal tablets.*

ALLEGED VIOLATION: On or about March 7, 9, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Dexedrine Sulfate tablets*, *Benzedrine Sulfate tablets*, *phenobarbital tablets*, and *Amytal tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *phenobarbital tablets* and the *Amytal tablets* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: May 30, 1951. A plea of nolo contendere having been entered, the court suspended the imposition of sentence and placed the defendant on probation without supervision for 1 year.

3443. Misbranding of thyroid tablets, diethylstilbestrol tablets, Dexedrine Sulfate tablets, and phenobarbital tablets. U. S. v. Willie D. Phillips (Phillips Bros. Drug Co.). Plea of nolo contendere. Sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30018. Sample Nos. 61895-K, 76415-K, 77701-K, 77711-K.)

INFORMATION FILED: January 31, 1951, Western District of Arkansas, against Willie D. Phillips, trading as the Phillips Bros. Drug Co., Ashdown, Ark.

INTERSTATE SHIPMENT: From the States of Missouri, New York, and Pennsylvania, into the State of Arkansas, of quantities of *thyroid tablets*, *diethylstilbestrol tablets*, *Dexedrine Sulfate tablets*, and *phenobarbital tablets*.

ALLEGED VIOLATION: On or about March 7, 9, and 13, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Dexedrine Sulfate tablets* and *phenobarbital tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *phenobarbital tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *diethylstilbestrol tablets* failed to bear labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.